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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,407	07/17/2003	Chris Saris	01017/35434B	2359
4743 7590 04/05/2007 MARSHALL, GERSTEIN & BORUN LLP 233 S. WACKER DRIVE, SUITE 6300 SEARS TOWER CHICAGO, IL 60606			EXAMINER O HARA, EILEEN B	
			ART UNIT 1646	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/05/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/622,407

Applicant(s)

SARIS, CHRIS

Examiner

Eileen B. O'Hara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 13,14,40,41,49,50,64 and 70-73 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13,14 and 64 is/are allowed.
- 6) ☒ Claim(s) 40, 41, 49, 50 and 70-73 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s).**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

1. Claims 13, 14, 40, 41, 49, 50, 64 and 70-73 are pending in the instant application. Claims 13, 14, 40 and 64 have been amended, claims 15, 17, 42-45 and 65-69 have been canceled and claims 70-73 have been added as requested by Applicant in the Paper filed December 20, 2006.

#### ***Withdrawn Objections and Rejections***

2. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

#### ***Maintained Rejections***

##### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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3. Claims 49 and 50 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 17 and 18 of U.S. Patent No. 6,627,199, for reasons of record in the previous office action. Applicants on pages 9-10 of the response traverse the rejection and submit that the rejection is in violation of 35 U.S.C. § 121, and also discuss MPEP § 804.01.

Applicants' arguments have been fully considered but are not deemed persuasive. The pending fusion protein claims correspond to the group that was prosecuted in the issued patent. The examiner is not making a double patenting rejection over two groups that had been restricted in the parent application.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 40, 41, 49, 50 and 70-73 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the polypeptides of SEQ ID NOS: 8 and 10 and fusion proteins thereof, does not reasonably provide enablement for polypeptide comprising an amino acid sequence at least 92% identical to the amino acid sequence of SEQ ID NOS: 8 or 10. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims, for reasons of record in the previous office action and below.

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Claims 40, 41, 49, 50 and 70-73 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for reasons of record in the previous office action and below.

The previous rejections were based on polypeptides that were broader in scope, and applicant has amended the claims to either obviate the rejection or change the scope to polypeptide comprising an amino acid sequence at least 92% identical to the amino acid sequence of SEQ ID NOS: 8 or 10. Applicants submit that new claims 70-73 are of similar scope to the issued polynucleotide claims in the parent application. However, claims 11, 12 and 15 of 6,627,199 are drawn to isolated nucleic acid molecules comprising a nucleic acid sequence that is at least 92% identical to the sequence of the nucleic acid molecule of SEQ ID NO: 7 or 9, which because of the degeneracy of the code, is narrower than 92% identity of one protein to another.

The nucleic acid molecule of SEQ ID NO: 9 is a splice variant of SEQ ID NO: 7 and encodes a protein of SEQ ID NO: 10, which is a secreted form of the receptor and is 180 amino acids in length. The polypeptides of SEQ ID NOS: 8 and 10 are identical for the first 170 amino acid residues. The specification teaches that the tmst2 receptor binds murine TRAIL specifically (example 9) and that the secreted form (SEQ ID NO: 10) blocked apoptosis in Jurkat cells induced by murine TRAIL protein (example 6). However, the claims encompass variants of these proteins that diverge substantially in structure, and only two proteins, a naturally occurring receptor and its soluble splice variant, which are identical over 94% of the extracellular domain

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that has the activity of binding murine TRAIL, have been disclosed. Since only the last 10 amino acids of the C-terminal differ in the soluble protein of SEQ ID NO: 10 from that of the full-length protein of SEQ ID NO: 8, the proteins are actually 100% identical in the extracellular region that has TRAIL binding activity. No other allelic or splice variant or homolog or ortholog has been disclosed.

The specification does not provide any working examples of any variants except for the splice variant, and there is limited guidance as to which amino acids, for example, could be substituted or deleted and still retain the TRAIL binding activity. Thus, the specification fails to teach the skilled artisan how to use the claimed polypeptides without resorting to undue experimentation to determine which variants would retain TRAIL binding activity.

For the reasons discussed above, due to the large quantity of experimentation necessary to generate the infinite number of derivatives recited in the claims and possibly screen same for activity, the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide activity, the absence of working examples and written description directed to same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the effects of mutation on protein structure and function, and the breadth of the claims which fail to recite any structural or functional limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope. Also, it cannot be established that a representative number of species have been disclosed to support the genus claim.

*New Rejections*

*Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 40, 41, 49, 50 and 70-73 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 70-73 encompass an isolated polypeptide comprising an amino acid sequence that is at least 92% identical to the amino acid sequence set forth in SEQ ID NOS: 8 or 10. Applicant on page 7 of the response submits that pages 11-12 and examples 6 and 9 support the 92% identical language. However, on page 11, lines 27-29 of the specification state: “a nucleotide sequences encode a polypeptide that is about 75 percent, or about 80 percent, or about 85 percent, or about 90 percent, or about 95, 96, 97, 98, or 99 percent identical to the polypeptide sequence as set forth in SEQ ID NOS: 8 or 10”. There is no recitation of a polypeptide that is at least about 92 percent identical to the polypeptide as set forth in SEQ ID NO: 8 or 10, and therefore this is new matter. Additionally, examples 6 and 9 support the activity of the receptor, but not the percent identity.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 40, 41 and 49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 40 and 49 recite “any one of claims, 13, 70-75 or 76”, and the last claim is 73, so it is not clear what is being claimed. Claim 41 is indefinite for depending from claim 40.

It is believed that all pertinent arguments have been answered.

***Conclusion***

7.1 Claims 13, 14 and 64 are allowed.

7.2 Claims 40, 41, 49, 50 and 70-73 are rejected.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37



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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (571) 272-0878. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nichol can be reached at (571) 272-0835.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://portal.uspto.gov/external/portal/pair>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Eileen B. O'Hara, Ph.D.

Patent Examiner



EILEEN B. O'HARA  
PRIMARY EXAMINER